REMARKS

I. THE STATUS OF THE CLAIMS

Claims 1-19, 21 and 22 are pending.

II. THE REJECTION UNDER 35 U.S.C. § 103

The final Office Action maintains the rejection of claims 1-17 and 19-22 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,374,659 ("Gowan, Jr."), U.S. Patent No. 5,834,019 ("Gergely et al."), U.S. Patent No. 6,569,463 ("Patel et al."), and U.S. Patent No. 5,980,882 ("Eichman"). In particular, the final Office Action maintains that it would have been obvious to select all of the elements as shown in the references to arrive at the instantly claimed liquid suspensions. Applicants respectfully traverse this rejection.

None of the cited references, alone or in combination, disclose or suggest the claimed invention. The claimed invention is a pharmaceutical aqueous suspension comprising:

> a) a therapeutically effective amount of suspended solid particles in crystal form comprising at least one active ingredient;
>
> b) a thickener;
>
> c) a uniformly dispersed nucleation inhibitor, wherein said nucleation inhibitor reduces growth rate of said active ingredient compared to suspensions not containing a nucleation inhibitor; and
>
> d) at least one amino polycarboxylic acid compound; and

wherein the suspension has a pH of about 3.7 to about 8.

Gowan discloses an aqueous pharmaceutical suspension that consists essentially of a substantially water-insoluble pharmaceutical active, xanthan gum; pregelatinized starch and polyoxyethylene sorbitan monooleate; a taste masking composition selected from the group consisting of sugars, sweet polyhydric alcohols, glycerin, artificial sweetener, flavoring agents and mixtures thereof; and water. See col. 2, lines 15-25. As recognized in the final Office Action, "[t]he reference fails to teach the active agent, Loratidine, the nucleation inhibitor, PVP, and the amino polycarboxylic acid, EDTA." Applicants respectfully submit that in addition, Gowan does not disclose or suggest a combination of elements that achieves the features recited in the claims.

Gergely, which merely discloses inherent properties of loratidine, including that it is water-insoluble and that it has a strong hydrophobic character (see col. 1, lines 22-33 and final Office Action at page 3), does not remedy the deficiencies in Gowan.

Patel, which merely discloses a number of laundry lists of possible ingredients in a **solid** composition, does not remedy the deficiencies in Gown or Gergely. For example, Patel discloses generally solid pharmaceutical compositions having a solid carrier including a substrate and an encapsulation coat on the substrate. See, e.g., col 3, line 61 to col. 4, line 8. Patel discloses that the solid carrier and/or the encapsulation coat can include different

combinations of active ingredients. Id. Patel discloses that the active ingredient in the pharmaceutical composition is **not** particularly limited and can be "hydrophilic, lipophilic, amphiphilic or hydrophobic." See col. 4, line 23 to col. 9, line 60. Patel discloses that the composition can optionally include one or more solubilizers to increase the solubility of the active ingredient; that one of sixteen preferred solubilizers is polyvinylpyrrolidone; and that more preferred solubilizers include sorbitol, glycerol, triacetin, ethyl alcohol, PEG-400, glycofurol and propylene glycol. See col. 29, lines 15-65. Patel discloses that the substrate can be "a powder or a multiparticulate; such as a granule, a pellet, a bead, a spherule, a beadlet, a microcapsule, a millisphere, a nanocapsule, a nanosphere, a microsphere, a platelet, a minitablet, a tablet or a capsule…" See col. 28, lines 20-55. Like Gowan and Gergely, Patel does not disclose or suggest a combination of elements that achieves the features recited in the claims.

Eichman discloses pharmaceutical compositions comprising a drug-resin complex and a chelating agent in which the composition is in the form of a solid or a gel. See Abstract. Eichman discloses that EDTA is known to stabilize drugs in solution by retarding their oxidation. See col. 2, lines 60-61. Eichman discloses that the drugs disclosed therein are not in solution. See col. 3, lines 57-61. Like Gowan, Gergely and Patel, Eichman does not disclose or suggest a combination of elements that achieves the features recited in the claims.

Applicants respectfully submit that the claimed combination of elements provides advantages to the claimed aqueous suspension over prior known aqueous suspensions. See the specification at, e.g., page 3, paragraph [011], page 11, paragraph [037], page 13, paragraphs [044] and [045], page 16, paragraph [056], page 23, paragraph [081] and Tables 1 and 2 and page 26, Summary of Results.

Reconsideration and withdrawal of the rejection of claims 1-17 and 19-22 under 35 U.S.C. § 103 as being obvious over "Gowan", Gergely, Patel and Eichman are respectfully requested.

III. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

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